NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JESSICA PENELOW and CHRISTINE BRANCACCIO, Plaintiffs, v. **JANSSEN PRODUCTS, LP**, Defendant.	Civil Action No. 12-7758 (ZNQ) (JBD) **OPINION**

QURAISHI, District Judge

THIS MATTER comes before the Court upon Defendant Janssen Products, LP's ("Janssen") Motion for Judgment as a Matter of Law ("Rule 50 Motion", ECF No. 473), Janssen's Motion for a New Trial ("Rule 59 Motion", ECF No. 474), and Relators Jessica Penelow and Christine Brancaccio's (collectively, the "Relators") Motion for Entry of Judgment ("Judgment Motion", ECF No. 475). Relators opposed Janssen's Rule 50 and Rule 59 Motions ("Rule 50 Opp'n Br." and "Rule 59 Opp'n Br.", ECF Nos. 481, 480), and Janssen replied ("Rule 50 Reply Br." and "Rule 59 Reply Br.", ECF Nos. 485, 486). Janssen opposed Relators' Motion for Entry of Judgment ("Judgment Opp. Br.", ECF No. 479), and Relators replied ("Judgment Reply Br.", ECF No. 488.) The Court has carefully considered the parties' submissions and decides the motions without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court: (1) grants in part, and denies in part,

Janssen's Motion for Judgment as a Matter of Law; (2) denies Janssen's Motion for a New Trial; and (3) grants in part, and denies in part, Relators' Motion for Entry of Judgment.

I. BACKGROUND[1]

Relators filed the instant action on behalf of the Government, twenty-six states and the District of Columbia, alleging fifty-six counts under the federal False Claims Act ("FCA"), the federal Anti-Kickback Statute, and the false claims act of various states ("state FCAs"). (*See* Second Am. Compl., ECF No. 90.) The claims arise from Janssen's purported kickback scheme and off-label ("OL") promotions of two HIV/AIDS drugs: Prezista and Intelence. (*Id.* ¶¶ 1–16.)

On May 6, 2024, a jury trial commenced on Relators' claims against Janssen. The jury received stipulated facts, substantial documentary evidence, and testimony from 12 fact witnesses and 5 expert witnesses. After a six-week trial, on June 13, 2024, the jury found Janssen liable for unlawfully promoting Prezista or Intelence under the federal FCA, as well as under each of the state FCAs. (Verdict Form, ECF No. 434.) The jury determined that Janssen submitted 159,574 claims in violation of the FCA and awarded $120,004,736 to the United States as a result of these violations. (*Id.* at 2.) Separately, the jury determined that Janssen submitted false claims in violation of the state FCAs, and awarded a lumpsum of $30,001,184 to the States, collectively, as a result of these violations. (*Id.* at 4–5.) Following the jury's verdict in favor of Relators on the federal FCA and state FCA claims, Janssen filed the instant renewed Motion for Judgment as a Matter of Law pursuant to Rule 50(b) and Motion for a New Trial pursuant to Rule 59. (ECF Nos. 473, 474). Relators, in turn, filed a Motion for Entry of Judgment. (ECF No. 475.)

The Court addresses Janssen's Rule 50 and Rule 59 Motions first, followed by Relators' Motion for Entry of Judgment.

[1] As the parties are familiar with the factual and procedural background of this matter, the Court omits most of the lengthy history of this over twelve-year-old case.

II. LEGAL STANDARD

A. Motion For Judgment as a Matter of Law

Judgment as a matter of law is appropriate where there is no "legally sufficient evidentiary basis" for a reasonable jury to find in favor of the prevailing party. Fed. R. Civ. P. 50(a); *see also Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) ("Such a motion should be granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability."). In considering the evidence, "the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." *Lightning Lube, Inc.*, 4 F.3d at 1166. "Although judgment as a matter of law should be granted sparingly, a scintilla of evidence is not enough to sustain a verdict of liability." *Id.* To that end, the proper inquiry on a motion for judgment as a matter of law is "whether there is evidence upon which the jury could properly find a verdict for [the prevailing] party." *Id.* (quoting *Patzig v. O'Neil*, 577 F.2d 841, 846 (3d Cir. 1978)). In other words, judgment as a matter of law should be granted if the record is "critically deficient of that minimum quantity of evidence from which a jury might reasonably afford relief." *In re Lemington Home for the Aged*, 777 F.3d 620, 626 (3d Cir. 2015) (quoting *Trabal v. Wells Fargo Armored Serv. Corp.*, 269 F.3d 243, 249 (3d Cir. 2001)). Finally, "[t]he burden on a defendant who raises a challenge to the sufficiency of the evidence is extremely high[.]" *State Farm Mut. Auto. Ins. Co. v. Lincow*, 444 F. App'x 617, 621 (3d Cir. 2011) (quoting *United States v. Riley*, 621 F.3d 312, 329 (3d Cir. 2010)).

B. Motion For a New Trial

Rule 59(a) provides that a court may award a new trial "after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court[.]" Fed. R. Civ.

P. 59(a). The purpose of a motion under Rule 59 is "to correct manifest errors of law or fact or to present newly discovered evidence." *Lazaridis v. Wehmer*, 591 F.3d 666, 669 (3d Cir. 2010) (quoting *Max's Seafood Café v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999)). Courts have the discretion to grant a new trial on several grounds, including: "(1) that the verdict is against the weight of the evidence; (2) that the damages are excessive; or (3) that the district court made substantial errors in the admission or rejection of evidence or in its instructions to the jury." *Winnicki v. Bennigan's*, Civ. No. 01-3357, 2006 WL 2506738, at *1 (D.N.J. Aug. 28, 2006) (citing *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, (1940)). Thus, "the decision whether or not to grant a new trial is committed to the sound discretion of the district court." *Id.* (citing *Wagner v. Fair Acres Geriatric Ctr.*, 49 F.3d 1002, 1017 (3d Cir. 1995)).

"[A] new trial should be granted only when the verdict is contrary to the weight of the evidence or when a miscarriage of justice would result if the verdict were to stand." *Brennan v. Norton*, 350 F.3d 399, 430 (3d Cir. 2003). A district court may not "grant a new trial because it would have come to a different conclusion than that reached by the jury." *Lyles v. Flagship Resort Dev. Corp.*, 371 F. Supp. 2d 597, 602 (D.N.J. 2005). Therefore, "[i]n determining whether the evidence is sufficient to sustain liability, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." *Lightning Lube, Inc.*, 4 F.3d at 1166. "The motion may be granted if 'the record is critically deficient of that minimum quantity of evidence from which a jury might reasonably afford relief.'" *Lyles*, 371 F. Supp. 2d at 602 (quoting *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 166 F. Supp. 2d 19, 28 (D.N.J. 2001)).

III. DISCUSSION

A. Janssen's Motion for Judgment as a Matter of Law

Prior to closing arguments, the Court held a conference with counsel to discuss the jury charge and jury verdict form. (*See* 6/11/24 Tr. at 7898:17–7916:17, ECF No. 454.) The parties raised a number of disputes regarding the jury instructions and verdict form. (*Id.*) With respect to Relators' state law claims, Relators asked the Court to instruct the jury that they "must also find" Janssen liable under every state FCA should the jury find Janssen liable under the federal FCA. (*Id.* at 7898:17–7916:17; *see* Proposed Jury Instructions 68, Disputed Instruction No. 25, ECF No. 424-1.) Janssen objected and asserted Relators had failed to provide a legal or factual basis for the state law claims. (*Id.*) While the Court ultimately accepted Relators' jury instruction on this charge over Janssen's objections, the Court expressed concerns regarding how Relators had presented the state law claims at trial. (6/11/24 Tr. at 7906:7–12.) Accordingly, the Court permitted Janssen to file a motion for judgment as a matter of law pursuant to Rule 50(b) post-trial should the jury find Janssen liable on the state law claims, and reserved on deciding the motion. (*Id.*)

Following the jury's finding in favor of Relators on the federal FCA and state FCA claims, Janssen moved for judgment as a matter of law pursuant to Rule 50(b). (ECF No. 473.) Janssen makes four primary arguments: (1) Relators failed to introduce evidence on which a reasonable jury could find that Janssen caused the submission of false claims, Janssen's OL marketing was material to the Government's payment decisions, and the at-issue claims were false under the False Claims Act; (2) Relators failed to prove that Janssen violated any of the state False Claims Acts; (3) the jury's verdict on the number of claims and amount of damages are arbitrary and based on unsupported evidence, and cannot otherwise be sustained because of critical errors; and (4) the

jury's verdict must be set aside because Relators' claims are barred under the government action and public disclosure bars of the FCA and by the Constitution. (Rule 50 Moving Br. 1–3, ECF No. 473-1.) The Court addresses each of these arguments in turn.

1. Jury's Finding of Liability Under the Federal False Claims Act

Janssen first contends that despite the jury's verdict finding that Janssen violated the FCA, this Court should enter judgment in its favor because Relators failed to prove the required elements of causation, materiality, and falsity under the FCA. (*See* Rule 50 Moving Br. 1–2, 7–37.) In support of its argument, Janssen asserts: (1) Relators "introduced no evidence on which a reasonable jury could find that Janssen caused the submission of false claims"; (2) Relators "introduced no evidence on which a reasonable jury could find that Janssen's alleged off-label marketing was material to the [G]overnment's payment decisions"; and (3) Relators "introduced no evidence on which a reasonable jury could find the at-issue claims were false." (*Id.* at 1–2.) In response, Relators contend that they introduced sufficient evidence to support the jury's findings on causation, materiality, and falsity. (Rule 50 Opp'n Br. 2–3, ECF No. 481.) After reviewing the evidence presented at trial, the Court finds there was a sufficient evidentiary basis for a reasonable jury to find Janssen liable under the FCA for the submission of false claims. Fed. R. Civ. P. 50(a).

With respect to causation, Relators were required to prove that Janssen's conduct was a "substantial factor" in inducing providers to submit claims for reimbursement from Medicare, Medicaid, or the federal AIDS Drug Assistance Program ("ADAP"), and that it was "reasonably foreseeable or anticipated as a natural consequence" that the submission of claims would result from Janssen's conduct. (*See* Final Jury Instructions 32, ECF No. 424-11); *United States ex rel. Penelow v. Janssen Prods., LP*, Civ. No. 12-7758, 2021 WL 6052425, at *9–10 (D.N.J. Dec. 21, 2021) (explaining "substantial factor" standard); *see also United States ex rel. Schmidt v. Zimmer*,

386 F.3d 235, 244 (3d Cir. 2004) (explaining "this Court applie[s] ordinary causation principles from negligence law in determining responsibility under the FCA" and, therefore, defendant's conduct must be "a substantial factor in bringing about" the filing of a false claim).[2]

At trial, Relators presented substantial evidence that Janssen trained and instructed its sales force to promote Prezista and Intelence OL, and that its sales force observed an increase in physicians' prescriptions after they delivered OL messages to physicians. (RXL78 at 2; 5/15/2024 Tr. at 1708:8–1709:13, 1726:20–1727:6, ECF No. 464; 5/22/2024 Tr. at 3255:15–3256:23, ECF No. 449; 5/23/2024 Tr. at 3508:4–16, ECF No. 457; 5/30/2024 Tr. at 4726:11–4727:23, ECF No. 467; 5/9/2024 Tr. at 748:25–749:13, ECF No. 463.) Relators also introduced marketing reports by a third-party marketing research firm that found that Janssen's sales force had the highest effectiveness of any sales force in causing "lift"—an increase in prescriptions through their promotion. (6/3/2024 Tr. at 5410:6–11, 5443:11–5444:6, 5447:2–6, 5448:10–5449:18, 5470:1–5477:9, 5480:25–5485:23, ECF No. 451.) In addition, Relators elicited expert testimony on causation in which witnesses opined on how Janssen encouraged OL marketing, thereby causing physicians to prescribe Prezista and Intelence OL. For example, pharmaceutical marketing expert George Sillup testified that Janssen's "off-label marketing caused physicians to prescribe Prezista and Intelence off-label," that Janssen's specific OL messaging "caused physicians to prescribe off-label for those specific reasons," and that Janssen's OL messaging directed at physicians "had

[2] Janssen argues that as part of the "substantial factor" test, Relators were required to prove that Janssen's conduct was the "but-for cause of the submission of any false claim." (Rule 50 Reply Br. 1, ECF No. 485.) Janssen, however, does not contest that the Court properly instructed the jury on the legal standard for causation, in which the Court instructed the jury to assess whether Janssen's conduct was a "substantial factor" in causing the submission of false claims to Medicare, Medicaid, and/or ADAP, and it was "reasonably foreseeable or anticipated as a natural consequence" that false claims would result from such conduct. (*See* Rule 50 Moving Br.; Rule 59 Moving Br.) As Janssen concedes that courts in the Third Circuit apply the "substantial factor" standard to assess causation in cases brought under the FCA, (Rule 50 Moving Br. 8), and that the jury instruction on causation was correct, the Court applies the "substantial factor" test in assessing whether Relators provided sufficient evidence of causation. *Zimmer*, 386 F.3d at 235.

a lasting impact on physicians' prescribing behavior." (5/22/2024 Tr. at 3046:24–3047:9.) Data expert Ian Dew further identified hundreds of thousands of "prescription drug event" data demonstrating physicians influenced by Janssen's OL marketing submitted claims for Prezista and Intelence to the Centers for Medicare & Medicaid Services ("CMS") and the Government for reimbursement. (*See* 5/31/24 Tr. 5222:2–5228:18, 5262:15–25, ECF No. 450; RX1480; DX5005; RX487; DX5009; RX1003.) Relators further introduced testimony from damages expert Israel Shaked, who performed statistical analyses and concluded that thousands of doctors who received Janssen's OL marketing prescribed the drugs OL at much higher rates than doctors who were not contacted by Janssen. (*See* 5/31/24 Tr. at 5409:3–5411:05, 5545:14–5552:11.)

Janssen contends that despite this substantial evidence, the record is insufficient to demonstrate causation because Relators did not present any "doctor-[specific] or patient-specific evidence to demonstrate the alleged off-label marketing effect on prescribing in any individual doctor's office." (Rule 50 Moving Br. 13, ECF No. 473-1.) Janssen raised this same argument at summary judgment and the Court squarely rejected Janssen's contention. *Janssen Prods., LP*, 2021 WL 6052425, at *9 (rejecting Janssen's argument that causation must be proven through patient-specific evidence and holding that Relators could prove causation by presenting "sufficiently detailed circumstantial evidence" that false claims were presented as a result of Janssen's conduct); *see also United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1037 (C.D. Cal. 2016) (holding that relator was not "required to identify a particular false claim" to prove causation under the FCA).

Here, examining the record before it, the Court finds that Relators produced sufficient evidence from which the jury could reasonably adduce that Janssen's OL marketing was a substantial factor in causing physicians to submit claims for reimbursement to Government payors,

and that it was reasonably foreseeable that false claims would result from such conduct. Relators proffered detailed documentary evidence, as well as expert and fact testimony, that demonstrated claims for Prezista or Intelence were submitted to the Government as a result of Janssen's OL marketing. Janssen raised challenges regarding the sufficiency, reliability and accuracy of Relators' proffered evidence at trial. (*See, e.g.*, 6/11/24 Tr. at 8091:3–8092:18). The jury evaluated both parties' arguments and concluded that Relators had sufficiently proven causation.[3] A reasonable jury could therefore have found that Janssen's OL marketing caused the submission of claims to the Government, and judgment as a matter of law is inappropriate on this issue. *See In re Lemington Home for the Aged*, 777 F.3d at 626 (explaining that the Court must give the non-moving party "the benefits of all reasonable inferences" when assessing a Rule 50(b) motion, "even though contrary inferences may be drawn" from the evidence).

Turning next to materiality, Relators were required prove that Janssen's OL marketing violations were material to the Government's payment decision. In other words, Relators were required to prove that Janssen's unlawful promotion "had a natural tendency to influence, or was capable of influencing, the payment or receipt of money or property." (Final Jury Instructions 34, Instruction No. 19.4.) The Court need only summarize some of the evidence Relators presented at trial on this issue. Relators introduced multiple Corporate Integrity Agreements ("CIA") and

[3] Janssen also argues that "Relators' theory of causation . . . is too remote from its causal agent . . . to satisfy the proximate cause requirement." (*See* Rule 50 Moving Br. 15–17.) The Court finds this argument unpersuasive. Fraud directed at physicians may establish FCA liability if reimbursement by the Government was a reasonably foreseeable result of the fraud. *See Marcus v. Hess*, 317 U.S. 537, 544 (1943) (concluding the FCA applies to fraudulent conduct that causes a third party to submit claims to the United States for amounts higher than would have been submitted); *United States v. Lagerbusch*, 361 F.2d 449, 449 (3d Cir. 1966) (holding that an employee was liable under the FCA for making false representations to obtain money from his employer, a government contractor reimbursed by the United States, and stating "[w]e have no doubt that the False Claims Act covers such an indirect mulcting of the [G]overnment."). The Court further notes that the jury was instructed on the requirement to find proximate cause, and Janssen does not contend this jury instruction was erroneous. (*See* Final Jury Instructions 32, Instruction No. 19.2 (explaining causation requires that the jury find that the submission of claims was "reasonably foreseeable or anticipated as a natural consequence" of Janssen's conduct); *see generally* Rule 50 Moving Br.)

Settlement Agreements that Janssen entered during the relevant period in order to resolve Government allegations concerning Janssen's OL marketing of prescription drugs, which Relators argued to the jury were evidence of materiality. (*See* RX423; RX361; RX1624; Rule 50 Opp'n Br. 20, ECF No. 481.) Relators elicited testimony from Janssen's president Glen Mattes who testified that OL marketing was illegal and material to the Government's payment decisions, including that if the Government "discovered that there was off-label marketing . . . and Medicare and Medicaid has [sic] reimbursed for those drugs . . . [the Government] will demand that money back." (5/22/24 Tr. at 2923:01–09; *see also id.* at 2930:08–12 (agreeing that "if there are products that are being sold for reimbursement by Medicare and Medicaid and it turns out that those were sold in violation of the law, the Government is going to come back and get its money").) Relators also introduced expert testimony from compliance expert Virginia Evans who testified that Government payors do not cover the cost of prescription products when they were provided in violation of the FCA, including for OL uses, and that if the Government pays for false claims under Medicare and Medicaid without knowledge of the fraudulent conduct, they will "attempt to recoup that money" after discovering such falsity. (5/28/24 Tr. at 3762:5–3763:22; 3796:01–23, ECF No. 458.) Relators introduced similar expert witness testimony from Sara Strand, who testified that Government payors would not pay for claims that were the result of OL marketing, and that if such a claim had been paid, the Government would require the manufacturer to reimburse the Government. (5/9/24 Tr. at 905:6–12.)

Janssen contends that Relators failed to prove materiality because: (1) "the federal [G]overnment has had full knowledge of Relators' allegations for over a decade, yet CMS is still paying for Prezista and Intelence;" (2) the Government had "actual knowledge of Relators' allegations;" and (3) Relators' proof of materiality consisted entirely of evidence that the

Government, and not necessarily CMS, generally cares about OL marketing, which fails to establish that the OL marketing would have altered CMS's payment decisions. (*See* Rule 50 Moving Br. 17–23.) Janssen appropriately raised these arguments during trial, including that "Medicare Part D pays for off-label" uses and medications, (6/11/24 Tr. at 8103:3–4), and that "CMS continues to reimburse" Prezista and Intelence despite awareness of Relators' allegations" (*id.* at 8063:2–6; *see also id.* at 8104:5–7 (arguing to the jury that "almost 200,000 prescriptions off-label were written for and paid for by prescribers who had nothing to do with [Janssen]"); *id.* at 5061:3–6 (arguing to the jury that "there isn't a shred of evidence in this case about what the Plan D sponsors evaluated when determining and certifying that a claim is reimbursable by Medicaid").) The jury considered both parties' arguments and determined that Janssen's OL marketing violations were material to the Government's payment decisions. As the Court may not "weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version," the Court is satisfied, based on the foregoing, that Relators presented sufficient evidence from which a reasonable juror could find that Janssen's OL marketing violations were material to the Government's reimbursement decisions. *Lightning Lube, Inc.*, 4 F.3d at 1166.

With respect to falsity, Relators were required to prove that the claims submitted to Medicaid, Medicare, or ADAP, or caused to be submitted by Janssen, were false. (Final Jury Instructions 31, Instruction No. 19.1). The Court instructed the jury that a claim made to a federal health care program, including Medicaid, Medicare or ADAP, is false "if it seeks reimbursement for a prescription that is not eligible for reimbursement." (*Id.* at 22, 31.) During trial, Relators introduced testimony from HIV expert Aaron E. Glatt, who opined that while Janssen promoted Prezista for treatment-naïve patients, Prezista's label was not indicated for treatment-naïve patients

from 2006–2008, nor did recognized compendia support the use of Prezista in treatment-naïve patients. (*See* 5/20/24 Tr. at 2329:24–2333:20, ECF No. 448.) Glatt also testified that while Janssen promoted Intelence for once-a-day dosing and for treatment-naïve patients, Intelence's label was only indicated for twice-a-day and for a "very specific group of experienced patients." (*Id.* at 2307:9–2315:23, 2316:8–19.) Relators also elicited testimony from Janssen's national sales director, Michael Iacobellis, who testified that prescribing Intelence for once-daily dosing was contrary to the drug's indicated label and that such messages would be "off-label" and not approved by the FDA. (5/14/24 Tr. at 1461:1–21, ECF No. 447.) In other words, Relators introduced evidence that demonstrated Janssen's marketing of Prezista and Intelence were OL, and that this OL marketing violated an express condition of payment for reimbursement under Medicare, Medicaid, or ADAP. Taken together, the Court finds that a reasonable jury could have found that claims for Prezista and Intelence submitted to Medicare, Medicaid, or ADAP were OL and ineligible for reimbursement.

After reviewing the record in full, the Court is satisfied that there is ample evidence to support the jury's verdict of liability under the FCA. It is not the Court's role to second-guess the jury's fact-finding and consideration of the evidence. Drawing all reasonable and logical inferences in Relators' favor, the Court finds that Janssen has failed to carry its high burden of demonstrating that "any verdict other than the one directed would be erroneous under the governing law" and therefore denies Janssen's Rule 50 Motion as to liability under the federal FCA. *Brownstein v. Lindsay*, 742 F.3d 55, 63 (3d Cir. 2014) (quoting *Macleary v. Hines*, 817 F.2d 1081, 1083 (3d Cir. 1987)); *see Klein v. Hollings*, 992 F.2d 1285, 1290 (3d Cir. 1993).

2. Jury's Finding of Liability Under the State False Claims Acts

In addition to finding that Janssen violated the FCA, the jury found that Janssen violated each of the twenty-seven state FCAs.[4] Janssen argues that the Court should grant Janssen judgment as a matter of law on the state law claims because Relators failed to present any evidence specific to Relators' state law claims. Janssen's argument is two-fold: 1) Relators failed to establish the coverage requirements of any of the state Medicaid and ADAP programs which have their own coverage schemes that are distinct from Medicare; and 2) Relators failed to prove causation, materiality and falsity as to these programs. (Rule 50 Moving Br. 38–43).[5]

As a preliminary matter, to the extent that Janssen contends the jury only considered potential liability stemming from the fraudulent submission of Medicaid and ADAP claims when assessing liability under the state FCAs, and not under the federal FCA, the Court rejects this notion.[6] (*See* Rule 50 Moving Br. 8–10, 38 (arguing that Relators' state law claims "implicates 'the conditions of payment' established by the respective states' Medicaid and ADAP programs" but that Relators' claims under the FCA implicates the conditions of payment established by Medicare Part D).) It is well-established that causing a physician to fraudulently submit a claim

[4] The twenty-seven state FCAs at issue are those of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia.

[5] Janssen also contends that the Court erred in instructing the jury that they must also find Janssen liable on the state law claims if they found Janssen liable on the federal FCA claim. (Rule 50 Moving Br. 40, n. 26.)

[6] At trial, for example, counsel for Janssen argued that in order for a state to recover damages for Medicaid fraud under the FCA, Relators' claims "have to be litigated . . . under the state False Claims Act." (6/11/24 Tr. at 7901:7–13.) As the Court explains above, this contention is incorrect. Many states have recovered, and continue to recover, in multi-state actions filed under the federal FCA without their own FCA statute. For example, Ohio and Kentucky have successfully recovered millions of dollars in Medicaid fraud actions, without having state FCAs. *See, e.g.*, AG Announces Settlement to Recover $446,800 for Ohio Medicaid Program, Circleville Herald (May 15, 2017), https://www.circlevilleherald.com/community/ag-announces-settlement-to-recover-for-ohio-medicaidprogram/article_341e1daf-fb18-5aa0-838b-f46b760f1029.html; Mark Payne, DaVita Healthcare Partners Settles Claims for $22 M, Washington Examiner (Jan. 8, 2015), https://www.washingtonexaminer.com/policy/healthcare/1221674/davita-healthcare-partners-settles-fca-claims-for-22m/.

to any federal healthcare program, including Medicaid and ADAP, can give rise to liability under the federal FCA. *See Universal Health Servs., Inc. v. United States*, 579 U.S. 176 (2016) (explaining that Medicaid is a "joint state-federal program" and that FCA liability may arise where a company causes the submission of fraudulent Medicaid claims); *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, Civ. No. 02-6074, 2005 WL 2667207, at *2–3 (N.D. Ill. Oct. 17, 2005) (discussing the legislative history of the FCA and explaining the FCA applies to "circumstances where claims are submitted to State, local, or private programs funded in part by the United States" including "claims submitted to state Medicaid agencies or intermediaries"). The Court thus properly instructed the jury that Medicare, Medicaid, and ADAP are each "federal health care programs" within the ambit of the FCA and that the submission of false claims under any of these programs could give rise to liability under the FCA. (Final Jury Instructions 22, 30–34, Instruction Nos. 17, 19.) Accordingly, when evaluating Janssen's liability under the FCA, the jury evaluated whether claims for Prezista or Intelence submitted under Medicaid and ADAP programs were false, caused by Janssen's unlawful conduct, and material to the Government's payment decisions.

Notwithstanding this fact, the Court agrees with Janssen that Relators failed to introduce sufficient evidence from which a reasonable juror could find Janssen liable on the state FCAs. During trial, Relators presented no evidence regarding the scope or elements of each state FCA, what type of fraudulent claims would lead to liability under these state FCAs, and what amount of damages each state suffered as a result of the statutory violations. Instead of introducing evidence specific to their state law claims, Relators premised their entire case on the legal argument that because Janssen's conduct violated the federal False Claims Act, Janssen's conduct also violated each of the analogous state statutes. (*See* Proposed Jury Instructions 68–69, Disputed Instruction No. 25; Rule 50 Opp'n Br. 50–56.)

At trial, Relators urged the Court to adopt a jury instruction that would direct the jury to find liability on all the state FCAs should the jury find liability under the FCA. (*See* 6/11/24 Tr. at 7898:17–7916:17; Proposed Jury Instructions 68–69, Disputed Instruction No. 25.) In proposing this jury instruction, Relators generally cited each state's FCA, but otherwise failed to provide the Court with any further analysis regarding the elements of each statute, their scope, or how they mirrored the FCA. (Proposed Jury Instructions 68–69, Disputed Instruction No. 25.) Relators cited to a single case in which the Government proposed a similar jury instruction. *See United States ex rel. Kester v. Novartis Pharm. Corp.*, Civ. No. 11-08196, ECF No. 476 (S.D.N.Y. July 2, 2015) (proposing the court instruct the jury that they must find defendant liable on all state FCAs should they find the defendant liable under the FCA). However, it is now clear that the case Relators relied upon settled before the parties could brief this proposed jury instruction, and it was never adopted by that court. *Id.* In fact, Relators cite to no authority in which a court actually made this finding, or adopted a similar proposed jury instruction, and the Court is further unaware of any such authority. (*See* Proposed Jury Instructions 68–69, Disputed Instruction No. 25; Rule 50 Opp'n Br. 50–56.)

While it appears that courts have occasionally observed that federal and state FCA claims "succeed or fail together," courts have generally only held so where "no party has alleged a material difference between the standards applicable to the FCA and equivalent state laws." *See, e.g.*, *United States ex rel. Travis v. Gilead Scis., Inc.*, 596 F. Supp. 3d 522, 543 n. 159 (E.D. Pa. 2022). Here, however, Janssen does challenge the congruence of the state FCAs to the FCA. (*See* 6/11/24 Tr. at 7898:17–7916:17; Proposed Jury Instructions 69–70, Disputed Instruction No. 25.) Janssen, for example, disputes whether false ADAP claims would give rise to liability under each state FCA. (Rule 50 Reply Br. 18, n. 14, ECF No. 485.) Because Janssen raised arguments

"specific to the state statutes," it was Relators' burden to articulate the elements of each state FCA, how each state FCA mirrored the federal FCA, and whether the state analog applied to fraudulent Medicaid and ADAP claims. *See U.S. ex rel. Portilla v. Riverview Post Acute Care Ctr.*, Civ. No. 12-1842, 2014 WL 1293882, at *9 (D.N.J. Mar. 31, 2014) (noting parallel outcomes on federal and NJFCA are appropriate where "the parties raise no arguments specific to the state statutes").

While the Court did adopt Relators' proposed instructions at trial, the Court also notes that before the parties' closing arguments, it specifically cautioned Relators regarding the lack of evidence they had introduced on their state law claims and emphasized that the Court's acceptance of Relators' verdict sheet should not be taken as acceptance that Relators' evidence was sufficient. The Court explained, in relevant part:

> I want to make sure that Relators are on notice that if there is a verdict of liability on those state claims, by no means are you covered by the fact that I've approved this verdict sheet. If anything, you might have actually caused yourself a greater issue because you've condensed this verdict sheet, where you're not allowing the jurors to allocate damages to each state, and you're not allowing them to make a determination as to the number of false claims per state. You're not even allowing them to determine the number of false claims for the states as a group.

(6/11/24 Tr. at 7906:15–25.) In fact, the Court predicted that this issue would become a focus of the parties' post-trial briefing. (*Id*. at 7906:9–12) ("I have some concerns about how the state law claims were presented during this trial, and I'm reserving on that decision because I have allowed Janssen to file a Rule 50 motion.").

After consideration of the parties' post-trial briefing and the trial evidence, the Court now finds that Relators failed to present sufficient evidence or analysis regarding the elements or scope of each state FCA at trial, despite the Court's warning prior to closing arguments, and that it was

error to accept Relator's proposed jury instruction.[7] As a result, the record is "critically deficient of that minimum quantity of evidence" from which a jury might find Janssen liable under the state FCAs. *In re Lemington Home for the Aged*, 777 F.3d at 626. Accordingly, the Court will grant judgment as a matter of law to Janssen on Relators' state law claims, and will vacate the jury's award of $30,001,184 to the States under the state FCAs.

To be clear, whether or not Relators carried their burden of proof under the state law claims has no bearing on the jury's finding of liability and damages under the federal FCA. In assessing Janssen's liability under the federal FCA, the jury independently determined that Janssen had caused the submission of 159,574 claims to the Government, and that the United States suffered $120,004,736 as a result of these violations. (Verdict Form 2; *see also* Final Jury Instructions, Instruction Nos. 26, 28; 6/11/24 Tr. at 7946:16–7947:24.) Accordingly, the damages the jury awarded to the States under the state FCAs is wholly severable from the damages the jury independently awarded to the United States under the federal FCA.

3. Jury Verdict on Damages

Janssen next argues that the jury's verdict on the number of claims and amount of damages cannot be sustained because: (1) the jury was instructed on the wrong measure of damages; (2) Relators' damages model was based on erroneous assumptions; (3) the number of claims and amount of damages are arbitrary and based on unsupported evidence; and (4) there is no basis to

[7] Relators also failed to prove by a preponderance of the evidence the damages each state suffered as a result of any violations of the state FCAs. Attesting to this failure, while the jury awarded the States a lumpsum award of $30,001,184, Relators provided the Court with no method of allocating this award among the state parties. (*See* Verdict Form.) During trial, Relators claimed they were in touch with the National Association of Medicaid Fraud Units ("NAMFCU"), and that NAMFCU could help distribute any lumpsum awarded to the States. (6/11/24 Tr. at 7899:15–19; 7902:15–20.) In Relators' post-trial briefing, however, other than vaguely asserting in a footnote that the States are "all . . . members of [NAMFCU]," Relators fail to detail NAMFCU's involvement in the instant action or how NAMFCU would allocate this award. (*See* Judgment Reply Br. 9, n.6, ECF No. 488).

identify the number of federal as opposed to state claims or damages. The Court finds each of these arguments unpersuasive.

a) Measure of Damages

Janssen first contends that the Court's instruction to the jury that the amount of damages is "the full amount paid by the Government" to Janssen "as the result of [the] false claims," (Final Jury Instructions, Instruction No. 26), was incorrect because under Third Circuit precedent, FCA damages are equal to "the difference in cost between that contracted for and that received." *United States v. Hibbs*, 568 F.2d 347, 351 (3d Cir. 1977). While the Third Circuit applies this measure of damages in certain cases brought under the FCA, it is more aptly employed, for example, where the Government has paid for goods or services that return a tangible benefit to the Government. *Hibbs*, 568 F.2d at 347 (applying this standard where "the damages [we]re essentially similar to those sustained when a defective article is purchased in a fraudulent transaction"). Here, however, the Government received no measurable or tangible benefit from Janssen's conduct. Janssen contends that the Government was conferred the benefit of "effective treatment for patients with HIV," but such an alleged benefit is intangible and impossible to calculate. (Rule 50 Moving Br. 45); *see U.S. ex rel. Feldman v. van Gorp*, 697 F.3d 78, 91 (2d Cir. 2012) (explaining that the "benefit of the bargain" standard is "not . . . the methodology generally employed by courts evaluating FCA claims based on Medicaid or Medicare fraud" and concluding that the appropriate measure of damages in such a case is "the full amount the [G]overnment paid based on materially false statements" because the Government received "no tangible benefit" from defendant's conduct); *United States ex. rel. Doe v. DeGregorio*, 510 F. Supp. 2d 877 (M.D. Fla. 2007) (holding that the damages were "the amount of money the Government paid out by reason of the false claims").

Here, because the Government did not receive any tangible or measurable benefit from Janssen's conduct, the Court finds that the proper measure of damages is the full amount the Government paid for the false claims, and that the Court did not err in instructing the jury on this measure of damages. *See United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (holding that where "[t]he [G]overnment offers a subsidy . . . with conditions" and "the conditions are not satisfied, nothing is due" and "the entire amount that [the defendant] received" for the false claims "must be paid back"); *see also United States v. Mackby*, 339 F.3d 1013, 1018 (9th Cir. 2003); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015).

b) Reliability of Relators' Damages Experts' Calculations

Janssen next argues that Relators' damages experts' calculations lacked factual basis and were based on erroneous assumptions. (Rule 50 Moving Br. 46–47.) As Relators point out, this is the third time that Janssen has raised such arguments challenging the reliability of the methodology employed by Relators' damages experts, and the Court has rejected Janssen's arguments each time. (*See* ECF No. 294 at 31–37; ECF No. 493; 6/10/24 Tr. at 7748:16–7749:23, 7753:12-16, ECF No. 470.) The Court declines to revisit these issues and maintains that the proper mechanism for Janssen's challenges to the assumptions and choice of methodology employed by Relators' damages experts was at trial during cross-examination. (ECF No. 493 at 7–9); *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) ("A party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination.") Indeed, Janssen was afforded multiple opportunities to cross examine Relators' expert witnesses during trial and did so at length. (*See* 6/3/24 Tr. at 5497:12–5593:7; 6/10/24 Tr. at 7732:18–7742:25; *see also* 6/7/24 Tr. at 7300:3–7307:11, 7345:4–7371:25, ECF No. 453; 6/10/24 Tr. at 7750:3–15.)

c) Basis of Jury Award

Janssen next contends that the number of claims and the amount of damages the jury awarded were arbitrary and based on unsupported evidence. A court reviewing a jury verdict has an "obligation . . . to uphold the jury's award if there exists a reasonable basis to do so." *Evans v. Port Auth. of N.Y. & N.J.*, 273 F.3d 346, 351-52 (3d Cir. 2001) (quoting *Motter v. Everest & Jennings, Inc.*, 883 F.2d 1223, 1230 (3d Cir. 1989)).

Here, the jury returned a verdict of $120,004,736 for Relators on the federal FCA violation and found that Janssen caused 159,574 false claims to be submitted in violation of the federal FCA.[8] (Verdict Form.) Janssen argues that because Relators' damages expert, Shaked, proposed that the jury find damages in either $446.7 million or $361.9 million, reflecting the submission of either 593,996 or 481,265 false claims, and the jury reached a different finding, the jury's award "rests on [] guesswork or speculation" and cannot be sustained. (Rule 50 Moving Br. 48–49.) The Court disagrees and finds that the evidence adduced at trial supports the jury's verdict to a reasonable degree of certainty. See *Evans*, 273 F.3d at 351–52. At trial, Relators presented evidence that established varying amounts of damages the Government incurred as a result of Janssen's OL marketing and promotion. (*See* ECF No. 481-2.) Relators, for example, presented differing damages estimates based on the type of drug and specific OL promotions the reimbursements were related to. (*Id.*)

The jury also heard testimony from Janssen's damages expert, Anupam Jena, who challenged the reliability of some of Shaked's data analyses, but testified that other parts of Shaked's estimates were "correct." (*See* 6/10/24 Tr. at 7617:11–7621:12; 6/7/24 Tr. 7316:1–22). Janssen further challenged the reliability and sufficiency of some of the damages data Relators

[8] Because the Court will grant judgment as a matter of law to Janssen on the state law claims, and will vacate the jury's award of $30,001,184 on these violations, the Court only addresses the jury's damages award under the FCA.

presented, including by arguing that the ADAP data Relators presented did not demonstrate that the prescribing physicians were contacted by Janssen. (*See* 6/11/24 Tr. at 8091–92.).

In light of the numerous challenges raised regarding Relators' proffered evidence of damages, "it was within the jury's realm, as the finder of the facts, to reject []the extreme figures proffered by the litigants as incredible and substitute an intermediate figure as a matter of its judgment from all of the evidence." *Fuji Photo Film Co. v. Jazz Photo Corp.*, 249 F. Supp. 2d 434, 453 (D.N.J. 2003), *aff'd*, 394 F.3d 1368 (Fed. Cir. 2005); *Cosimano v. Twp. of Union*, Civ. No. 10-5710, 2017 WL 1395493, at *3 (D.N.J. Apr. 17, 2017) (explaining a jury is "free to accept or reject the figure calculated by Plaintiff's expert" and that the jury "can choose to reduce the expert's number based upon such things as their determination as to her credibility or the underlying assumptions upon which the calculations were made"). Mindful of its role to be "deferential to a jury's damages verdict," the Court finds that there was a reasonable basis from which the jury could conclude that Janssen caused the submission of 159,574 false claims in violation of the federal FCA, and that the Government sustained $120,004,736 in damages as a result. *Leonard v. Stemtech Int'l Inc.*, 834 F.3d 376, 392 (3d Cir. 2016).

d) Number of False Claims

Janssen further argues that because Relators' state law claims fail as a matter of law, the jury's finding of the number of claims cannot be sustained because it includes federal and state claims, with no basis in the record to disaggregate them. (Rule 50 Moving Br. 49.) This contention is incorrect. As the Court noted *supra* III(A)(2), whether or not Relators carried their burden of proof under the state law claims has no bearing on the jury's finding that Janssen's conduct caused the submission of false Medicare, Medicaid, or ADAP claims under the federal FCA.

While Relators ultimately failed to carry their burden on the proving the state law claims, the jury reasonably found that Janssen's conduct violated the FCA and that Janssen caused the

submission of 159,574 false claims to the Government. The jury instructions and question two of the Verdict Form were clear in directing the jury to only identify the number of false claims that were submitted to the Government, and not to identify any claims that were submitted to the states. (*See* 6/11/24 Tr. 7946:16–7947:24 (confirming that the jury must only identify "the number of false or fraudulent claims that were submitted to the United States").[9] Accordingly, the Court finds that the number of claims the jury identified as false or fraudulent under the FCA can be sustained, notwithstanding the Court's granting of judgment as a matter of law on Relators' state law claims.

Drawing all reasonable and logical inferences in the nonmovant's favor, the Court finds that Janssen fails to meet its heavy burden of showing that "a miscarriage of justice would result if the verdict were to stand" on the FCA claim. *Klein*, 992 F.2d at 1290. Accordingly, Defendant's Motion for Judgment as a Matter of Law will be denied as to this issue.

4. Government Action and Public Disclosure Bars

Finally, Janssen argues that this Court has no subject matter jurisdiction under the FCA's government action and public disclosure bars. (Rule 50 Moving Br. 52–53.) Specifically, Janssen contends that: (1) the government action bar precludes Relators claims because Janssen entered a CIA with the Government in 2010 to settle allegations related to the OL marketing of another drug; and (2) the public disclosure bar precludes Relators' claims because allegations related to the OL marketing of other drugs were publicly disclosed in connection with two CIAs that Janssen executed in 2010 and 2013. Janssen's arguments are unpersuasive.

[9] Jury Instruction No. 28 was initially drafted to instruct the jury to identify "the number of false or fraudulent claims that were submitted to the United States, *the states, and the District of Columbia*." (Final Jury Instructions 45, Instruction No. 28.) Prior to delivering the written instructions to the jury, counsel for Relators confirmed that this instruction should be revised to remove mention of "the states, and the District of Columbia" and should only instruct the jury for a finding on the "number of false or fraudulent claims that were submitted to the United States." (6/11/24 Tr. 7946:16–7947:24.)

The government action bar is inapplicable to the instant case because Relators' allegations were not "the same as allegations already made by the [G]overnment" and were not "based on the same underlying facts." *See Sturgeon v. Pharmerica Corp.*, 438 F.Supp.3d 246, 262 (E.D. Pa. 2020). Here, assuming the 2010 CIA is sufficient to trigger the government action bar under the FCA, the Government's allegations which led to the 2010 CIA related to the alleged OL marketing of the drug Topamax—not Prezista or Intelence—and were thus substantially dissimilar to Relators' claims here. *See* RX423; *Sturgeon*, 438 F.Supp.3d at 262 (explaining that a relator's allegations must be "similar enough to be characterized as feeding off of the [G]overnment's allegations" for the government action bar to apply and that the bar does not apply where a relator seeks to "remedy fraud that the [G]overnment has not yet attempted to remedy").

With respect to the public disclosure bar, after Janssen filed its Rule 50 Motion, the United States filed a statement of interest, exercising its right to object to dismissal of this action based on the public disclosure bar for FCA claims accruing on or after March 23, 2010.[10] (U.S. Statement of Interest, ECF No. 478.)

The public disclosure bar of the FCA provides in relevant part:

> The court shall dismiss an action or claim under this section, *unless opposed by the Government*, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed – (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

[10] The FCA's public disclosure bar was amended on March 23, 2010. Congress amended the FCA in 2010 and in so doing "overhauled the public disclosure bar," "radically chang[ing] the 'hurdle' for relators." *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 298 (3d Cir. 2016). In *Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010), the Supreme Court held that this amendment was not retroactive. Thus, it applies only to FCA claims accruing on or after the effective date of the amendment.

31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis added).

Because the public disclosure bar of the FCA provides that the Court shall dismiss an action "*unless opposed by the Government*," and here, the Government exercised its right by objecting to such dismissal, the Court denies Janssen's motion to dismiss this action on these grounds. *Id.*

Janssen also asks the Court to hold that the *qui tam* provisions of the FCA are unconstitutional because it represents an impermissible delegation of executive power to a private party. (Rule 50 Moving Br. 54–55.) Janssen relies on a recent decision in the Middle District of Florida in which the district court departed from the longstanding and nationwide consensus that these provisions do not violate the separation of powers, and instead held that the *qui tam* provisions are an unconstitutional exercise of executive power. *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, Civ. No. 19-1236, 2024 WL 4349242 (M.D. Fla. Sept. 30, 2024). The Court declines to follow this singular non-precedential and out-of-circuit court decision, and instead follows every federal circuit court of appeals that has addressed this issue and holds that the FCA's *qui tam* provisions are constitutional. *United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787 (10th Cir. 2002); *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001) (en banc); *United States ex rel. Taxpayers Against Fraud v. General Elec. Co.*, 41 F.3d 1032 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743 (9th Cir. 1993); *see also United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148 (2d Cir. 1993).

B. Janssen's Motion for a New Trial

Janssen also moves for a new trial pursuant to Rule 59 and raises many of the same arguments it raises in its Rule 50 Motion. (*See generally* Rule 50 Moving Br.; Rule 59 Moving Br., ECF No. 474-1.) Janssen argues that Relators failed to prove elements of their FCA and state

FCA claims, and that these failures of proof, exacerbated by errors in at least three of the Court's jury instructions, "created an atmosphere of confusion for the jury" that justifies a new trial. (Rule 59 Moving Br.)

1. Jury's Finding of Liability Under the Federal False Claims Act

Janssen first contends, as it did in its Rule 50 Motion, that Relators failed to prove causation, materiality, and falsity of a claim under the FCA, and that this evidentiary failure warrants a new trial. Although the standard for granting a new trial is "less demanding" than the standard for granting judgment as a matter of law, the Court finds that even under the less demanding standard, Janssen has failed to establish that the jury's finding of liability under the federal FCA is contrary to the great weight of evidence. *Boehringer Ingelheim Vetmedica, Inc.*, 166 F. Supp. 2d at 28; *Dougherty v. Marshalls of MA, Inc.*, 460 Fed. Appx. 132, 135 (3d Cir. Jan. 26, 2012) (explaining where a motion for a new trial is based predominantly on the weight of the evidence, the motion should be granted "only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks [the] conscience.") As the Court explained *supra* III(A)(1), Relators presented substantial evidence at trial that supports the jury's findings on causation, materiality, and falsity under the FCA. Thus, with respect to the jury's finding of liability under the FCA, the Court finds that the record does not show that the jury's verdict resulted in a miscarriage of justice or shocks the conscience. *Dougherty*, 460 F. App'x at 135.

2. Purported Errors in the Jury Instructions

Janssen next contends that three of the Court's instructions to the jury—Instruction No. 23 (Federal and State FCAs), Instruction No. 26 (Measure of Damages), and Instruction No. 22 (FDA Approval)—contained errors that the jury proved unable to navigate in delivering its verdict. (Rule 59 Moving Br. 3–4.)

The standard for ordering a new trial based on a claim of erroneous jury instructions is high. "A new trial on the ground of erroneous jury instructions is permissible only when it is clear that an error in [the] instructions as a whole was such as to have misled the jury." *New Idea Farm Equip. Corp. v. Sperry Corp.*, 916 F.2d 1561, 1567 (Fed. Cir. 1990). In reviewing jury instructions, the court must consider the entire trial record, because "instructions take on meaning from the context of what happened at trial, including how the parties tried the case and their arguments to the jury." *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1522 (Fed. Cir. 1995), *rev'd on other grounds*, 520 U.S. 17 (1997).

As discussed *supra* III(A)(3)(a), the Court finds that Instruction No. 26, which instructed the jury on the measure of damages, was proper. With respect to Instruction No. 22, Janssen argues that the instruction "effectively instructed the jury to ignore the undisputed testimony of Dr. Amit Patel," who testified that standard practice in the industry interpreted silence from the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") as approval. (Rule 59 Moving Br. 4.) Jury Instruction 22 instructed:

> You have heard testimony from a Janssen employee, Dr. Amit Patel, about the FDA's silence in response to certain of Janssen's promotional advertising submissions regarding Prezista and lipids. You also heard him testify that Janssen considered the FDA's silence in response to those advertising submissions as the FDA's indirect or tacit approval of Janssen's advertising. I am instructing you that there is no statute or regulation that says that the FDA's silence means that it has approved a promotional advertising submission.

Janssen contends that the Court erred in not including the language "or disapproved" as Janssen proposed including in its proposed jury instructions. (Rule 59 Moving Br. 12–13 (explaining Janssen's proposed language would have clarified "there is no statute or regulation that says that the FDA's silence means that it has approved *or disapproved* a promotional

advertising submission.").) Janssen argues that the Court's failure to include Janssen's proposed language improperly influenced the jury to find scienter and falsity. (*Id.*)

The Court is not persuaded there was any error in this jury instruction. Janssen does not challenge the accuracy of this jury charge, but rather asserts this jury charge was somehow misleading because the Court did not adopt Janssen's exact proposed language. However, "[a] trial judge is not required to adopt the exact wording of a point for charge submitted by counsel." *Posttape Associates v. Eastman Kodak Co.*, 537 F.2d 751, 757 (3d Cir.1976). Rather, a court assesses whether the jury charge, taken as a whole, accurately instructed the jury. *See Colegrove v. Cameron Mach. Co.*, 172 F. Supp. 2d 611, 634 (W.D. Pa. 2001) ("[i]f the jury charge, taken as a whole, accurately instructed the jury, then there is no error in [the Court] rejecting a party's suggested point for charge in favor of another statement of the applicable law.") Here, the Court finds that it accurately instructed the jury on this issue, and the Court's omission of the phrase "or disapproved" did not mislead the jury. In fact, adopting Janssen's proposed language would have had the very misleading effect Janssen now attempts to raise in its motion. The Court rightfully rejected it.

With respect to Instruction No. 23, for the reasons outlined *supra* in III(A)(2), the Court agrees with Janssen that it was error to adopt Relators' instruction. The Court must accordingly determine whether this error had a "substantial influence" on the jury's remaining verdict of liability under the federal FCA. *United States v. Thornton*, 1 F.3d 149, 156 (3d Cir. 1993), *cert. denied*, 510 U.S. 982 (1993) (quoting *United States v. Hill*, 976 F.2d 132, 145 (3d Cir.1992) (a new trial is only warranted when "the[ ] errors, when combined, so infected the jury's deliberations that they had a substantial influence on the outcome of the trial"); *see also Inter Med. Supplies Ltd. v. EBI Med. Sys., Inc.*, 975 F. Supp. 681, 686 (D.N.J. 1997), *aff'd and remanded*, 181 F.3d 446 (3d

Cir. 1999) (citation omitted) ("[E]ven if the court determines that an error was made, it should not grant a new trial unless it also determines that the error was so prejudicial that []refusal to take such action appears to the court inconsistent with substantial justice"). In this case, the jury's finding of liability under the federal FCA was independent of its finding of liability under the state FCAs. The jury was first tasked with determining liability under the FCA *before* it could then determine whether Janssen violated the state FCAs. In other words, had the Court properly instructed the jury that liability on the state analogs did not necessarily follow liability on the FCA, it is "highly probable" that the jury's finding of liability under the FCA would have been the same. *Forrest v. Beloit Corp.*, 424 F.3d 344, 349 (3d Cir. 2005) (citing *McQueeney v. Wilmington Trust Co.,* 779 F.2d 916, 924 (3d Cir.1985) (an error is harmless if it is "highly probable" that it did not affect the outcome of the case). The Court thus finds that although it adopted Instruction No. 23, the Court did not fail to apprise the jury of Relators' burden of proof under the FCA, nor did the Court confuse the jury as to its role in identifying the number of false claims that were submitted to the Government.

After reviewing the evidence in full, the Court cannot conclude that the jury's verdict was against the great weight of the evidence on the FCA claim. On the state law claims in which the Court is overturning the jury's verdict and finding that judgment as a matter of law should be granted in favor of Janssen, a new trial is not warranted because the Court's decision effectively resolves these issues. *See Lucent Techs., Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 257 (D. Del. 2001) (overturning the jury's verdict and granting judgment as a matter of law on certain issues but nonetheless denying motion for a new trial because the court's decision was "sufficient to resolve [any] issues").

3. Jury Deliberations and Verdict

Janssen's final argument in support of its Rule 59 Motion is that the jury's damages award reflects an "improper compromise verdict" because the number of claims and damages found by the jury are "untethered to any evidence presented at trial." (Rule 59 Moving Br. 38–39.) Janssen further points to the "timeline of communications from the jury during deliberations" and the fact that the jury concluded its deliberations on a Thursday evening just before 5 PM, as evidence that the jury was "forced to compromise on an impermissible global damages figure because such evidence was not available, and because certain members of the jury were not available to deliberate the following day." (*Id.* at 41–42.) The Court finds these arguments unavailing.

As discussed *supra* III(A)(3), the Court finds that there exists a reasonable basis and sufficient evidence underlying the jury's verdict and findings. Furthermore, Janssen's speculations as to whether the jury rushed in its deliberation is without merit. The jury deliberated for over two full days, and reached a unanimous verdict, awarding damages in an amount far less than what Relators sought. The Court is convinced that the jury properly discharged its duty in evaluating the evidence, and that the jury's verdict was reasonable in light of the evidence presented. *See Lockhart v. Westinghouse Credit Corp.*, 879 F.2d 43, 54 (3d Cir. 1989) (rejecting defendant's contention of compromise verdict stating that, on review, court must ascertain "only whether the jury's verdict is reasonable in light of the evidence presented, and not to indulge in unsubstantiated and speculative assertions"), *overruling recognized on other grounds*, *Starceski v. Westinghouse Electric Corp.*, 54 F.3d 1089, 1099, n.10 (3d Cir. 1995).

Having presided over the trial in this matter and having carefully reviewed the arguments and evidence presented by counsel in connection with this Rule 59 Motion, the Court finds that Janssen fails to raise any arguments sufficient to justify the "extraordinary relief" of granting a new trial, and the Court declines Janssen's invitation to "usurp[] the jury's prime function as the

trier of fact[.]" *Boehringer*, 166 F. Supp. 2d at 29; *Marra v. Phila. Housing Authority*, 497 F.3d 286, n. 18 (3d Cir. 2007). The jury's verdict finding Janssen liable under the FCA was not against the weight of the evidence; rather, it was in accordance with the weight of the evidence. The jury was tasked with determining which of the parties' accounts was more credible, bearing in mind Relators' burden of proof on each of its claims. The jury carried out its duty to evaluate the evidence and assess the credibility of all the witnesses. There was an abundance of evidence to support the jury's verdict in favor of Relators on the FCA claim. *See United States v. Copple*, 24 F.3d 535, 547, n.17 (3d Cir. 1994). As such, the Court does not find that a miscarriage of justice would result if the jury's verdict as to liability and damages under the FCA stands. *See Brennan*, 350 F.3d at 430. Accordingly, Janssen's Motion for a New Trial will be denied.

C. Relators' Motion for Entry of Judgment

Having addressed Janssen's Rule 50 and Rule 59 Motions, the Court next turns to Relators' Motion for Entry of Judgment. (*See generally* Judgment Moving Br., ECF No. 475-1.)

1. Trebling of Damages

Under the FCA, a defendant is liable for "3 times the amount of damages which the Government sustains because of the [defendant's] act." 31 U.S.C. § 3729(a)(1); *Cook Cnty., Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119, 122 (2003) ("[I]f the [FCA] claim succeeds, the defendant is liable to the Government for . . . treble damages"); *Yates v. Pinellas Hematology & Oncology*, P.A., 21 F.4th 1288, 1297 (11th Cir. 2021) (observing that the FCA "mandat[es] the imposition of treble damages"). The jury found that the Government suffered $120,004,736 in damages as a

result of Janssen's conduct. As such, the Court will enter judgment in the amount of $360,014,208 against Janssen.[11]

2. Civil Penalties

In addition to compensatory damages, the FCA requires that the Court assess civil penalties against Janssen based on the number of false claims that they submitted. Under the FCA, the Court must assess a fine between $5,500 and $11,000 per false claim.[12] 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9). It is within this Court's discretion whether to impose the maximum, the minimum, or some intermediate penalty. *Cook Cnty, Ill.*, 538 U.S. 119, 132 (2003); *see also United States v. Rogan,* 02-3310, 2006 WL 8427270, at *25 (N.D. Ill. Oct. 2, 2006) ("Though the imposition of civil penalties are mandatory, 31 U.S.C. § 3729, the court determines the amount of the penalty.")

In making this determination, courts look to the totality of the circumstances, including the egregiousness of the conduct, the Government's damages, the right of the Government to be made completely whole, and general fairness principles. *See United States ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 501 F. Supp. 2d 51, 56 (D.D.C. 2007). Additionally, courts fixing civil penalties generally will consider the gravity of the offense, a defendant's acceptance of responsibility or lack of remorse, the need for deterrence, and possible recidivism. *See United States v. Saavedra*, 661 Fed. App'x 37, 46 (2d Cir. 2016); *Amerigroup Illinois, Inc.*, 488 F. Supp. 2d at 740. Relators seek a statutory violation of $9,000 per claim, whereas Janssen requests that

[11] Janssen again contends that the "entire federal damages figure is invalid" because "some portion of the jury's federal damages award must be based on federal funding for the state claims that underlie the jury's state damages award." (Judgment Opp'n Br. 17–18.) As discussed *supra* III(A)(2), the jury's award of damages to the Government under the FCA is wholly severable from the damages the jury awarded to the States as a result of the state FCA violations.

[12] Congress has since increased the civil penalty range for an FCA violation. *See* 28 C.F.R. § 85.5. However, a penalty range of $5,500 to $11,000 was the range in effect during the relevant time period. 28 C.F.R. § 85.3(a)(9); (Judgment Moving Br. 7, n.4). Accordingly, the Court applies this range in assessing a penalty.

the Court's penalty assessment be "limited to no more than an amount equal to the actual damages found by the jury." (Judgment Moving Br. 36; Judgment Opp'n Br. 40, ECF No. 479.)

a) The Number of False Claims

Janssen contends that any penalty imposed should not be based on "the number of claims those physicians and Plan Sponsors ultimately made to healthcare programs," but on "the conduct in which Relators allege Janssen engaged," because "the verdict form is hopelessly unclear" regarding the number of false claims submitted to the Government. (Judgment Opp'n Br. 25–28, n.5.) The Court finds this argument unavailing.

As noted *supra* III(A)(3), the jury found Janssen caused the submission of 159,574 false claims to the Government, and Relators' failure to independently prove their state law claims does not vitiate this finding in any manner. The Court is further unpersuaded by Janssen's argument that assessing a penalty based on the number of false claims physicians submitted would improperly punish Janssen "for the acts of others." (Judgment Opp'n Br. 26.) It is well-established that liability under the FCA extends to third parties whose fraudulent conduct causes the submission of false claims to the Government. *See Marcus*, 317 U.S. at 544. Janssen reaped significant benefits from its fraudulent conduct, and Janssen cannot escape the correspondingly significant penalties mandated by the FCA by simply arguing that it was not the actual party submitting claims to the Government. *See Lagerbusch*, 361 F.2d at 449 ("We have no doubt that the False Claims Act covers such an indirect mulcting of the [G]overnment."). Accordingly, the Court determines the penalty to be assessed based on the jury's finding that Janssen caused the submission of 159,974 false claims to the Government.

b) The Penalty

In enacting the FCA and mandating "significant" damages, Congress determined that an FCA violation is a serious offense and that a civil penalty within the express statutory range was

necessary for the effective operation of the FCA. *U.S. ex rel. Chandler v. Cook County, Ill.*, 277 F.3d 969, 977 (7th Cir. 2002) ("It could not be more clear that Congress, in adopting [the FCA damages scheme] addressed the situation with careful precision as to what sort of damage scheme was necessary to achieve the goals of the statute"). The Court is thus mindful of its role to grant "substantial deference to the broad authority that legislatures necessarily possess in determining the types and limits of punishments for crimes," and declines to impose a penalty below the minimum statutory range, as Janssen requests this Court do. *U.S. v. Bajakajian*, 524 U.S. 321, 334 (1998) (quoting *Solem v. Helm*, 463 U.S. 277 (1983)); (Judgment Opp'n Br. 30–33 (arguing that the Court should impose a "1:1 ratio as a benchmark" for the relationship between actual damages and any assessed penalties).)

The facts in the record support a civil penalty near the middle of the statutory range of $5,500 and $11,000. The Court is convinced that Janssen engaged in a deliberate and calculated scheme that spanned several years and involved the unlawful marketing of its products. The evidence at trial also demonstrated that Janssen was aware of the seriousness of its conduct, and entered into at least three agreements with the Government in the past to resolve allegations related to OL marketing of other drugs. *See* RX423; RX361; RX1624. Further, despite the jury's verdict, Janssen refuses to accept responsibility for its conduct. *See Saavedra*, 661 Fed. App'x at 46 (affirming the district court's award of maximum statutory penalties where defendant issued a press release following the jury's verdict showing "a disturbing refusal to accept responsibility"). Following the jury's verdict, Janssen issued a press release stating the jury's decision was "predicated on a clearly erroneous jury instruction that is contrary to the law" and that Janssen is "confident [the jury's verdict] will be reversed on appeal." Zoey Becker, *J&J to seek appeal of $150M verdict in long-spanning HIV meds off-label marketing case*, FiercePharma (June 17,

2024), https://www.fiercepharma.com/marketing/jjs-janssen-seek-appeal-150m-verdict-long-spanning-hiv-meds-false-claims-act-litigation.

While the need for deterrence, possible recidivism, Janssen's evidenced pattern of misconduct, and its refusal to accept responsibility counsel in favor of the Court imposing a higher civil penalty, the lack of evidence regarding patient harm and general fairness principles counsel against the Court imposing the maximum penalty. For example, while Janssen's OL marketing may have caused harm to some patients, Relators presented no evidence that any such harm resulted. The Court is also mindful of its duty to impose a fine that is not "grossly disproportionat[e] to the gravity of [the] defendant's offense." *Bajakajian*, 524 U.S. at 334 (holding that a fine violates the Excessive Fines Clause of the Eighth Amendment "if it is grossly disproportional to the gravity of a defendant's offense").

Balancing these factors, the Court finds that a penalty near the middle of the statutory range both reflects the seriousness of the offense, and is not so grossly disproportionate to the jury's finding of actual damages that it would constitute excessive punishment or a breach of due process under the U.S. Constitution. (*See* Judgment Opp'n Br. 3–4, 28); *Yates*, 21 F.4th at 1314 (observing that "[penalties] falling below the maximum statutory fines for a given offense . . . receive a strong presumption of constitutionality").

The Court thus imposes a fine of $8,000 for each false claim under the FCA. Such a penalty would amount to over ten times the actual damages suffered by the Government, which the Court finds adequately serves Relators' interests and reflects the seriousness of the offense without being unfair to Janssen. *See United States v. Saavedra*, Civ. No. 11-6425, 2015 WL 7621481, at *1–2 (S.D.N.Y. June 16, 2015), *aff'd*, 661 F. App'x 37 (2d Cir. 2016) (awarding $11,000 per false statement which amounted to a civil penalty of eleven times the actual damages suffered by the

Government where the defendant's conduct was "deliberate" and the defendant refused to accept responsibility for his actions). The jury found 159,574 false claims. As such, the Court will award $1,276,592,000 in civil penalties.

IV. CONCLUSION

For the reasons stated above, the Court will **GRANT IN PART** and **DENY IN PART**, Janssen's Motion for Judgment as a Matter of Law. The Court will **DENY** Janssen's Motion for a New Trial. The Court will **GRANT IN PART** and **DENY IN PART** Relators' Motion for Entry of Judgment. An appropriate Order and Judgment consistent with this Opinion will follow.

Date: March 28, 2025

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE